

AMENDMENTS TO THE DRAWINGS:

Replace Figure 1 with the following amended drawing sheet. Figure 1 has been amended to give the hole reference numeral "14".

REMARKS

The Examiner is thanked for the due consideration given the application. A substitute abstract is attached to this paper. A substitute drawing sheet containing revised Figure 1 is attached to this paper. The specification has been amended to insert headings and to improve the language.

Claims 12-17 are pending in the application. Claim 12 has been amended to better set forth the claimed invention. Claims 13-17 have been amended to improve their language in a non-narrowing fashion.

No new matter is believed to be added to the application by this amendment.

**Rejection Under 35 USC §112, Second Paragraph**

Claims 14-17 have been rejected under 35 USC §112, second paragraph, as being indefinite. This rejection is respectfully traversed.

The Official Action asserts that claims 14 and 17 lack full antecedent basis. Claims 14 and 17 have been amended to have full antecedent basis.

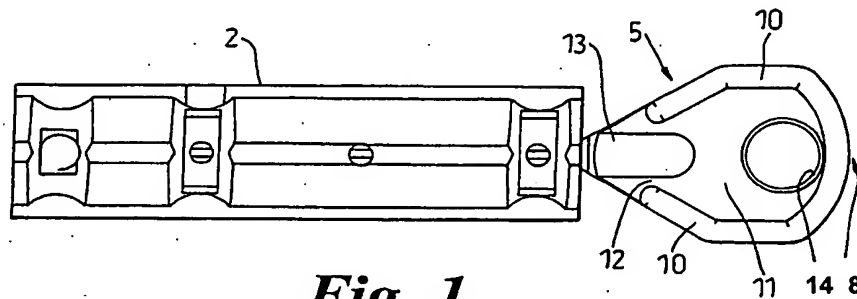
The Official Action asserts that claim 15 lacks a clear transitional phase. Claim 15 has been amended to have a clear transitional stage and positive method steps.

The claims are thus clear, definite and have full antecedent basis. This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

### Art Rejections

Claims 12-14 have been rejected under 35 USC §102(b) as being anticipated by CROSSMAN (GB 2 352 403). Claims 12 and 14 have been rejected under 35 USC §103(a) as being unpatentable over LEVIN et al. (U.S. Patent 6,168,606) in view of HIGGINS (U.S. Patent 3,358,689). Claims 15-17 have been rejected under 35 USC §103(a) as being unpatentable over CROSSMAN in view of HIGGINS. These rejections are respectfully traversed.

The present invention pertains to the design of a twist off cap or tab on a lancet that is illustrated, by way of example, in Figure 1 of the application, which is reproduced below.

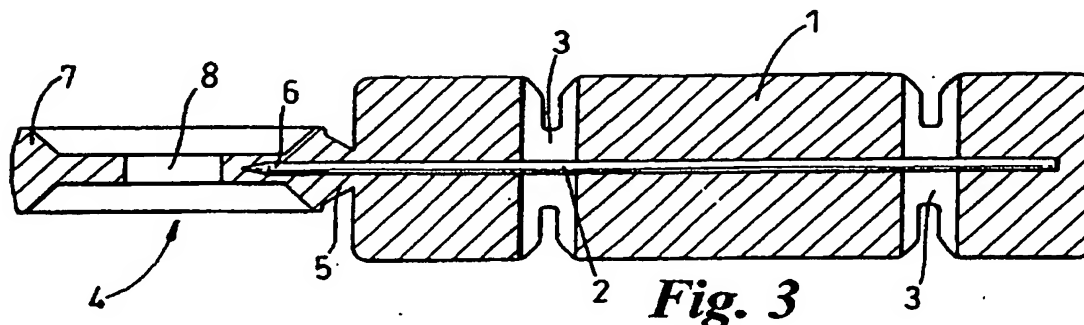


**Fig. 1**

The twist off cap or tab is designed with a thickened outer peripheral rib 10 which is spaced from another thickened region 13 which surrounds the tip of the lancet, by a region of thinner section 11. The thinner section 11 restricts or chokes the flow of molten plastics material as it moves towards the needle and beyond to form the lancet body. The outer peripheral thickened region 11 means that upon entering the mold, the

plastic enters a relatively large cross-sectional area before it is choked down by the thinner section 11 and then released into the section by the needle.

CROSSMAN pertains to a lancet. The Official Action refers to Figure 3 of CROSSMAN, which is reproduced below.

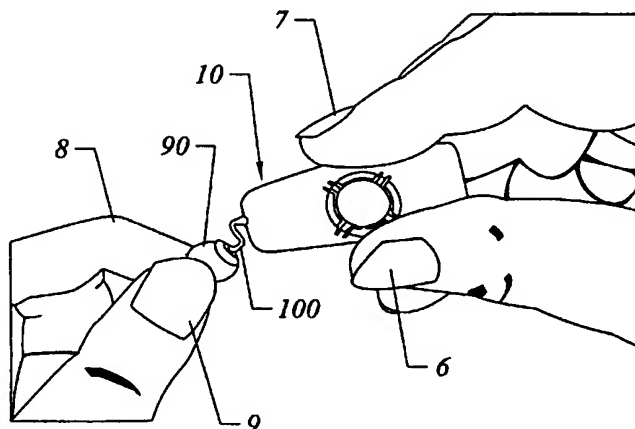


In CROSSMAN, the tab 4 is disc shaped with a hole 8 at the center of a thickened circumferential region. However, in this design the thickened region extends 360° around the disc and there is no interruption to the flow caused by a thinner section. The Official Action asserts that if you traverse the section in the direction of the axis of the needle, you would start off with a thickened section, followed by a thinner section, followed by a thicker section adjacent the needle.

In contrast, claim 12 of the present invention recites: "said removable guard portion having an outer peripheral thickened region describing a generally U- or C-shape, a central region of thinner section and a further thickened region being spaced from the adjacent ends of the peripheral thickened region such that there is a gap therebetween bridged only by said

thinner section." These features are clearly neither disclosed nor inferred by CROSSMAN.

LEVIN et al. pertain to a single use lancet. The Official Action refers to Figure 5 of LEVIN et al., which is reproduced below.



**FIG. 5**

Figure 5 of LEVIN et al. shows a needle guard connected via a thin flexible stem 100 to a bulbous spherical pull tab 90. This bulb and stem are utterly different from the guard portion recited in claim 12 of the present invention.

The teachings of HIGGINS fail to compensate for the deficiencies of CROSSMAN and LEVIN et al.

As a result, CROSSMAN fails to anticipate claim 12 of the current invention. One of ordinary skill would not produce claim 12 of the present invention from a knowledge of the teachings of CROSSMAN or LEVIN in view of HIGGINS. A *prima facie*

case of unpatentability has thus not been made. Claims depending upon claim 12 are patentable for at least the above reasons.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

**Conclusion**

The Examiner is thanked for considering the Information Disclosure Statement filed December 21, 2004 and for making an initialed PTO-1449 Form of record in the application.

Prior art cited but not utilized is believed to be non-pertinent to the instant claims.

The rejections are believed to have been overcome, obviated, or rendered moot, and no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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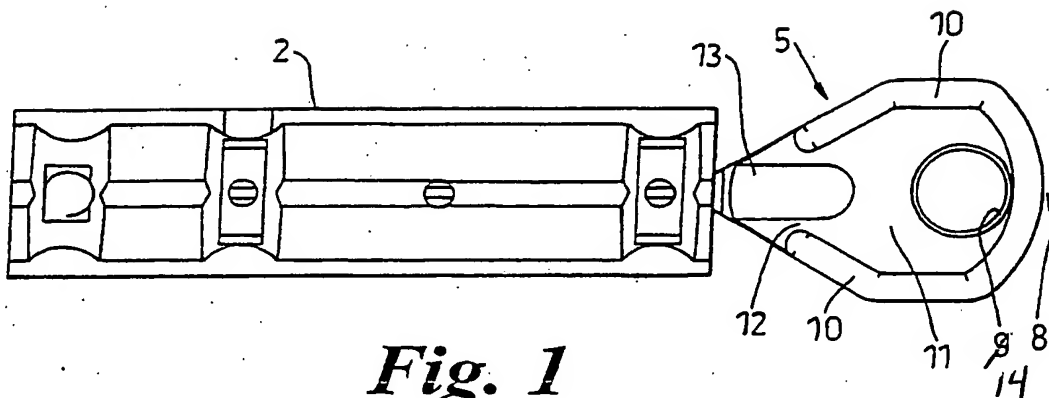
**APPENDIX:**

The Appendix includes the following items:

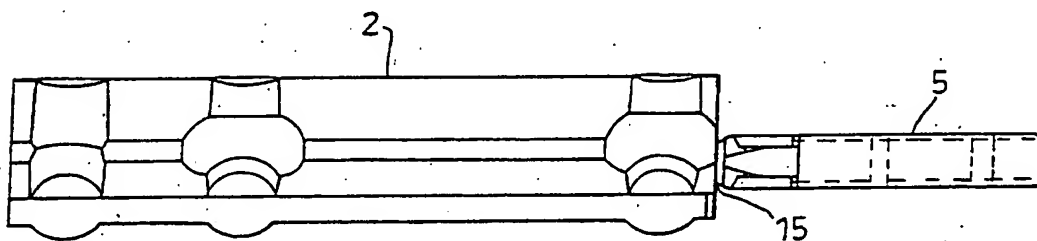
- amended Abstract of the Disclosure
- a Replacement Sheet for Figure 1 of the drawings



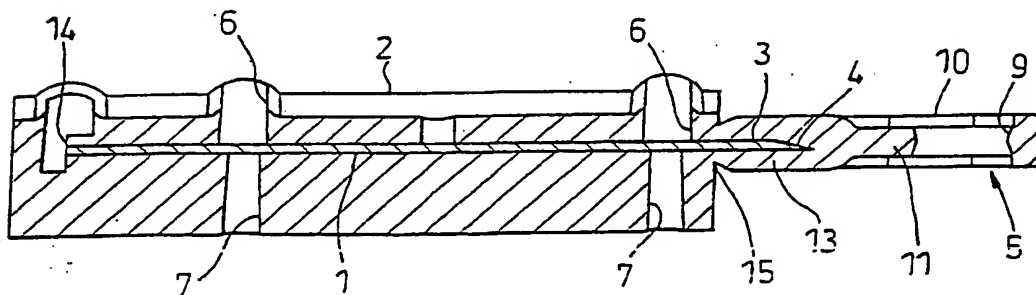
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*Fig. 1*



*Fig. 2*



*Fig. 3*